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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BRISTOL, LYNN ANNE	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,122	LAUS ET AL.	
	Examiner	Art Unit	
	Lynn Bristol	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner's Comments

1. It is noted that Claims 13-16 depend from 6, whereas it seems that the claims would more properly depend from Claim 3. Thus for purposes of this restriction, the Examiner has grouped these claims as depending from claim 3.

2. While both Claims 21and 23 appear to be directed to different forms of cancer treatment, the method steps for each of the claims seems to include two separate inventions: the first invention in each of steps (a) for both Claims 21 and 23 is for determining susceptibility to an immunotherapeutic composition; and the second invention in each Claims 21 and 23 is for treating/administering the immunotherapeutic composition to the subject found to be susceptible. Notably, Claim 28 is drawn to a distinct and separate method for determining susceptibility to an immunotherapeutic composition in a cancer subject. For purposes of the restriction, the Examiner has grouped Claims 21 and 23 on the basis of their administering steps.

3. Claim 22 is a multiple dependent claim, which depends from other multiple dependent claims, Claims 17 and 18; Claim 27 is a multiple dependent claim, which depends from other multiple dependent claims, Claims 17 and 18; and Claim 30 is a multiple dependent claim, which depends from other multiple dependent claims, Claim 17-20. Accordingly, the Examiner has withdrawn claims 22, 27 and 30 from restriction.

Election/Restrictions

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-20, drawn to an immunotherapeutic composition comprising antigen presenting cells (APCs) activated, *ex vivo*, with a protein conjugate having as either of the N- and C-terminal moieties a tumor-associated antigen (TAA) such as prostatic acid phosphatase (PAP) and an APC binding protein such as GM-CSF, classified in class 435, subclass 1.1 or class 424, subclass 93.1.

II. Claim 21, drawn to a method of treating cancer comprising administering an immunotherapeutic composition to the cancer subject, classified in class 435, subclass 375 or class 424, subclass 93.1.

III. Claims 23-26, drawn to a method of inhibiting cancer growth by stimulating a subject APCs *ex vivo* with a protein conjugate and administering stimulated APCs to the subject, classified in class 435, subclass 375 or class 424, subclass 93.1.

IV. Claims 28 and 29, drawn to a method of determining susceptibility to an immunotherapeutic composition comprising determining the grade of cancer in a subject as a, classified in or class 424, subclass 93.1.

The inventions are independent or distinct, each from the other because:

5. The methods of Inventions II-IV differ in the method objectives, method steps and parameters, intended populations and in the reagents used. The methods for each of Groups II-IV are different for the following reasons: Group II requires administering to a

cancer patient with differentiated cancer cells, a therapeutic dose of an immunotherapeutic composition in order to treat the cancer to where there is a 10% reduction; Group III requires that antigen presenting cells (APCs) are isolated from a cancer patient with differentiated cancer cells, that the cells are stimulated in vitro with an protein conjugate having different N- and C-terminal moieties to the extent that the APCs activate T-cells to produce a cytotoxic response greater than that obtained by stimulation with either the N- or C-terminal moiety alone in order to inhibit cancer cell growth to where there is a 10% reduction; and Group III requires isolating cancer cells from a cancer patient, staging the cancer cells for the state of differentiation and determining based on the state of differentiation the susceptibility of the cancer subject to an immunotherapy composition. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions of Groups II-IV are separate and distinct as having different method steps, intended populations and reagents used in performing the methods, and are patentably distinct.

6. Inventions of Group I and Groups II-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the activated APCs of Group I could be used in unrelated ex vivo methods, where T cells isolated from any patient requiring an antigen-specific T-cell response, are stimulated in

vitro with the APCs, followed by adoptive transfer of the activated T cells into the subject patient. Additionally, the APCs could be used in immunoassays for screening antibodies, or they could be administered to an unrelated species to produce antibodies, in addition to being used in a materially different process. As for the method of treating a cancer patient (Group II) and the method of inhibiting cancer cell growth (Group III), the APCs could be substituted for any art recognized therapy known to be effective in treating or inhibiting the specific type of cancer cell, e.g., chemotherapy, antisense, gene therapy, small molecule drugs, radiation, hormone therapy, etc. As for the method of determining susceptibility of a cancer to the APCs, one could readily substitute APCs for another therapeutic agent in screening for susceptibility, as for example, in identifying a surface expressed molecule on a cancer (e.g., HER-2) and whether the cells are susceptible to HERCEPTIN. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions of Groups I-IV are separate and distinct as there being no requirement to perform the methods with the product, and are patentably distinct.

7. These inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because searches in the patent literature would not be co-extensive and thus burdensome on the Examiner, restriction for examination purposes as indicated is proper.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. If any one of Groups I, III or IV is elected, then species (cancer) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A) soft tissue carcinomas

Specie B) lymphoma

Specie C) cancers of the brain

Specie D) esophagus

Specie E) uterine

Specie F) cervix

Specie G) bone

Specie H) lung

Specie I) endometrium

Specie J) bladder

Specie K) breast

Specie M) larynx

Specie N) colon/rectum

Specie O) stomach

Specie P) ovary

Specie Q) pancreas

Specie R) adrenal gland

Specie S) prostate

The species A-S do not share a common utility nor do they have a substantial structural feature common amongst them. Each of the cancers of species A-S can originate from any number of different cell types (e.g., epithelial, endothelial or mesothelial). Also, the cancers being associated with different organs are nevertheless, under the influence of different growth factors and hormones. Additionally, numerous studies have shown that receptor density and affinity for different therapeutic biomolecules is highly variable amongst different tissues and organs, in addition to there

being differences to the extent to which biomolecules are able to penetrate cancers. Thus, species A-S are patentably distinct cancers. Additionally, searching all of the species would be burdensome for the examiner because the searches would not be co-extensive as a result of each of the cancers having obtained a separate status in the art.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1, 23 and 28 are generic to the species A-S.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER